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Re: Patent Term Extension
Application for
U.S. Patent No. 4,844,882

CORRECTED NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,844,882, filed December 29, 1987 and issued July 4, 1989, which claims the medical device ALBUNEX®, is eligible for patent term extension under 35 U.S.C. § 156. In view of the decision of the Court of Appeals for the Federal Circuit in Merck & Co. v. Kessler, 38 USPQ2d 1347 (1996), the period of extension has been recalculated to extend the term of the patent from its 20-year expiration date instead of the 17-year expiration date. Since the 20-year expiration date of the patent is later than the 17-year expiration date and since the 14 year limit applies in both situations, the recalculation results in a shorter extension under 35 U.S.C. § 156 using the 20-year expiration date. The recalculated period of extension has been determined to be 220 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of March 2, 1995. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\ &= \frac{1}{2} (975 - 537) + 1422 \\ &= 1641 \text{ days}\end{aligned}$$

Since the regulatory review period began January 14, 1988, before the patent issued (July 4, 1989), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 14, 1988 to July 4, 1989 is 537 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $975 - 537 = 438$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (August 5, 1994) when added to the period of extension calculated above (1641 days) cannot exceed fourteen years. The period of extension is thus limited to August 5, 2008, by operation of 35 U.S.C. § 156(c)(3). Since the patent term of twenty years from filing (35 U.S.C. § 154) would expire on December 29, 2007, the period of extension is the number of days to extend the term of the patent from its expiration date to and including August 5, 2008, or 220 days.

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The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of ~~750~~ days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,844,882
Granted:	July 4, 1989
Applicant:	Kenneth J. Widder
Owner of Record:	Molecular Biosystems, Inc.
Title:	CONCENTRATED STABILIZED MICROBUBBLE-TYPE ULTRASONIC IMAGING AGENT
Classification:	424/9.52
Product Trade Name:	ALBUNEX®
Term Extended:	220 days


H. Bernstein

Hiram A. Bernstein
Senior Legal Advisor
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Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: ALBUNEX®
FDA Docket No. 94E-0360